



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/520,022   | 01/23/2006  | Bror Morein          | 67185-78227                 | 5079                   |
| 23432 7590 11/27/2007<br>COOPER & DUNHAM, LLP<br>1185 AVENUE OF THE AMERICAS<br>NEW YORK, NY 10036 |             |                      | EXAMINER<br>CHEN, CATHERYNE |                        |
|  |             |                      | ART UNIT<br>1655            | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>11/27/2007     | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/520,022 | <b>Applicant(s)</b><br>MOREIN ET AL. |  |
|                              | <b>Examiner</b><br>Catheryne Chen    | <b>Art Unit</b><br>1655              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 3, 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1655

### **DETAILED ACTION**

The Amendments filed on Sept. 12, 2007 has been received and entered.

Currently, Claims 1-14 are pending. Claims 1-5, 10-14 are examined on the merits.

### ***Election/Restrictions***

Claims 6-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Jan. 31, 2007.

Applicant's election with traverse of Group I (claims 1-5, 10-14) in the reply filed on Jan. 31, 2007 is acknowledged.

### ***Claim Objections***

Claim 13 is objected to because of the following informalities:

In Claim 13, the word "the" is repeated twice.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What is meant by "which fraction may be a different one in the different complexes." Clarification is required.

### ***Response to Arguments***

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (US 6352697 B1) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference fails to state that different types of saponin fractions may be integrated into different iscom matrix particles.

Cox et al. teaches a saponin vaccine preparation comprising Quillaja saponaria from 50% to 70% by weight of Fraction A of Quil A and from 50% to 30% by weight of Fraction C of Quil A (column 14, lines 26-38, column 16, lines 9-14). A method of preparing an immunostimulatory complex (iscom), which comprises admixing a saponin preparation according to saponins Quillaja saponaria comprising from 50-70% by weight of Fraction A of Quil A and from 50-30% by weight of Fraction C of Quil A (Claims 10, 11). Peptides can be incorporated into iscoms either directly or by chemical coupling to a carrier protein after incorporation of the carrier protein into iscoms (column 1, lines 40-56). This whole complex confers the immunostimulatory effects. Table 1 shows fractions A, B, and C of Quil A displaying different iscom forming ability and adjuvant activity. Cox et al. show that particular combinations of fraction A and C result in a saponin preparation which has the desirable properties of A and the benefits of C (column 5, lines 25-31). Thus this shows that different types of saponin fractions are used to form different iscoms.

Art Unit: 1655

Table 5 shows virus and iscoms, virus and iscom-matrix, and virus alone as adjuvants to confer immunogenicity. Thus the reference teaches that there are different types of iscoms with different types of formulations and different proteins to form the desired iscom matrices.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (WO96/11711) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference fails to state that different types of saponin fractions may be integrated into different iscom matrix particles. Cox et al. teaches saponin preparation of saponins of Quillaja saponaria from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C (claims 1-3), fractions A, B, and C (page 7, line 24). A method of preparing an immunostimulatory complex (iscom), which comprises admixing a saponin preparation according to saponins Quillaja saponaria comprising from 50-70% by weight of Fraction A of Quil A and from 50-30% by weight of Fraction C of Quil A (Claims 10, 1). Cox et al. teaches iscoms are Immuno Stimulating Complexes, where the typical iscom is estimated to contain 5 to 10% by weight Quil A, 1 to 5% cholesterol and phospholipids, and the remainder proteins. Peptides can be

Art Unit: 1655

incorporated into iscoms either directly or by chemical coupling to a carrier protein after incorporation of the carrier protein into iscoms (column 1, lines 40-56). This whole complex confers the immunostimulatory effects. Table 1 shows fractions A, B, and C of Quil A displaying different iscom forming ability and adjuvant activity. Cox et al. show that particular combinations of fraction A and C result in a saponin preparation which has the desirable properties of A and the benefits of C (column 5, lines 25-31). Thus this shows that different types of saponin fractions are used to form different iscoms. Table 5 shows virus and iscoms, virus and iscom-matrix, and virus alone as adjuvants to confer immunogenicity. Thus the reference teaches that there are different types of iscoms with different types of formulations and different proteins to form the desired iscom matrices.

### ***Double Patenting***

Applicant is advised that should claim 2 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1655

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Patent Examiner  
Art Unit 1655

/Susan Hoffman/  
Primary Examiner, Art Unit 1655  
November 21, 2007